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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,727	09/14/2005	Martin Krause	BB-124	1308
23557 7590 12/03/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER MEAH, MOHAMMAD Y				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
12/03/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/518,727

**Applicant(s)**

KRAUSE ET AL.

**Examiner**

MD. YOUNUS MEAH

**Art Unit**

1652

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 22, 24-34 is/are rejected.
- 7) ☒ Claim(s) 7 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/08 has been entered.

Claims 1-8, 22-34 are pending. Claims 1-8 were examined in the previous action. With supplemental amendment of this application filed 9/2/08, the applicant amended claims 1, 2, and 6, canceled claims 9-21 and added new claims 22-34 for further examination.

### ***Claim objections***

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of claim 6 from which it is dependent. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of claim 1 from which it is dependent. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 7 and 23 will not be considered further on their merit and therefore will not be examined.

***Claim Rejection***

***35 U.S.C 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2-5 and 22-28 (dependent on claim 1), 6 and 7-8, 29-34 ( dependent on claim 6) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "the peptides labeled in step d" in part e)" as there is insufficient antecedent basis for the peptides labeled in step d, from which it depends.

Claim 6 is indefinite in the recitation of "the peptides labeled in step d" in part e)" as there is insufficient antecedent basis for the peptides labeled in step d, from which it depends.

***CLAIM Rejection - 35 U.S.C 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8 were rejected under 35 U.S.C. 102(b) as being anticipated by Aebersold et al. (WO 00/11208) for the reasons set forth in the prior office action mailed on 04/01/08.

Claims 1-6, 8 and new claims 22 and 24-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Aebersold et al. (WO 00/11208, from IDS).

Aebersold et al. teach method of identification and quantification of protein in sample by cleaving the protein to peptides using proteolytic enzyme (page 18, paragraph 4) and using a reagent A-L-PRG, wherein A linked to solid support (wherein, A comprises biotin, oligohistidine, etc, page 12) and covalently linked to linker L (L contain metal bound chelate, page 14, 2<sup>nd</sup> paragraph and may contain disulfide group, which is cleavable, page 6, last paragraph.); PRG comprise sulfhydryl group, enzyme substrate (page 6, 2<sup>nd</sup> paragraph.) N- hydroxysuccinimide ester groups, etc (claim 32 of Aebersold et al.) to bind to the cleaved peptides. Aebersold et al. teach the use of tandem technique comprising electrospray ionization Mass spectrometry coupled with liquid chromatography (HPLC/ESI-MS/MS (FIG 7), peptide sequence information (page 19, 2<sup>nd</sup> paragraph.) combined with isotope and metal-ion chelate tag for qualitative and quantitative analysis of protein in a sample. Aebersold et al. teach the use chelated metal ion in their L for enhanced ionization in Mass spectrometric analysis. Since Aebersold et al. A-L-PRG (similar to applicants' A-Y-PRG) comprise chelated metal ion in their L and Aebersold et al. teach the use of stable isotope as well as metal ion ( Na ion page 38 paragraph 3 and Table 5 page 73) as standard in Mass spectrometric analysis, their methods anticipate applicants inventions in claims 24-26, 30-34. Although

Aebersold et al. teach the use linker L having labeled with isotope, they do not label the proteins with said isotope. Therefore Aebersold et al. also anticipate applicants' inventions of claims 22 and 29.

Applicants' argument on page 13 of their amendments of 09/02/08 is fully considered but not found to be persuasive. Applicants argue that Aebersold et al. use stable isotopes tag and use sulfhydryl group to bind cysteine containing protein and whereas applicants invention use metal-ion chelate tag. As explained above Aebersold et al. use A-L-PRG (similar to applicants A-Y-PRG, wherein Y comprises metal-ion chelate) reagent wherein L comprise both isotope and metal-ion chelate. Like applicant, Aebersold et al use sulfhydryl group of PRG to bind the peptide. Therefore Aebersold et al. anticipate applicants' inventions.

Applicants' argument on page 13 of their amendments of 09/02/08 is fully considered, but they not found persuasive. Applicants argue that Aebersold et al. use stable isotopes tag and use sulfhydryl group to bind cysteine containing protein and whereas applicants invention use metal-ion chelate tag. As explained above Aebersold et al. use A-L-PRG (similar to applicants A-Y-PRG, wherein Y comprises metal-ion chelate) reagent wherein L comprise both isotope and metal-ion chelate. Like applicant, Aebersold et al use sulfhydryl group of PRG to bind the peptide. Therefore Aebersold et al. anticipate applicants' inventions.

***Allowable Subject Matter/Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NASHAAT T NASHED can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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